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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/590,447	06/09/00	FORMAN	B 1/302 (HL)

ALLERGAN INC  
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HM22/0625

EXAMINER

HUI, S

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application N .

09/590,447

Applicant(s)

FORMAN ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 31-40(in part), drawn to a method of treating a pathological condition, including hypercholesterolemic by employing compound of formula (1), classified in class 514, subclass 211.08, 211.15, 212.01, 217.05, and 218.
- II. Claims 1-13, 31-40 (in part), drawn to a method of treating a pathological condition, including hypercholesterolemic by employing compound of formula (2), classified in class 514, subclass 226.8, 227.5, 256, 252, 239.5, 315, and 438.
- III. Claims 1-13, 31-40 (in part), 14-30, drawn to a method of treating a pathological condition, including hypercholesterolemic by employing compound of formula (3), classified in class 514, subclass 211.08, 211.15, 212.01, 217.05, and 218.
- IV. Claims 1-13, 31-40 (in part), drawn to a method of treating a pathological condition, including hypercholesterolemic by employing compound of formula (4), classified in class 514, subclass 226.8, 227.5, 256, 252, 239.5, 315, and 438.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I, II, III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mode of operations. The invention of Group I operates by the employment of compounds of formula (1); the invention of Group II operates by the employment of compounds of formula (2); the invention of Group III operates by the employment of compounds of formula (3); and the invention of Group IV operates by the employment of compounds of formula (4).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### ***Election of species***

Claims 1-40 are generic to a plurality of disclosed patentably distinct species comprising a method of treating a pathological condition by employing a compound of formula (1), (2), (3), or (4). The compounds recited in the claims are a generic representation of multiple patentably distinct species such as, for example:

For compound of formula (1) and (3):

When  $X = CH_2$ ,  $Y = \text{phenyl}$ ,  $A = CH_2$ ,  $B = H$ ,  $R_3 = H$ ,  $R_4 = CH_3$  and  $R'_3 = (R_{15})_r\text{-azepinyl}$  where  $R_{15} = H$ , the compound is classified in class 514, subclass 212.01;

When  $X = NH_2$ ,  $Y = \text{phenyl}$ ,  $A = CH_2$ ,  $B = H$ ,  $R_3 = H$ ,  $R_4 = CH_3$  and  $R'_3 = (R_{15})_r\text{-azepinyl}$  where  $R_{15} = H$ , the compound is classified in class 514, subclass 217.05;

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When  $X = CH_2$ ,  $Y = \text{phenyl}$ ,  $A = CH_2$ ,  $B = H$ ,  $R_3 = H$ ,  $R_4 = CH_3$  and  $R'_3 = (R_{15})_r$ -diazepinyl where  $R_{15} = H$ , the compound is classified in class 514, subclass 211.08;

When  $X = NH_2$ ,  $Y = \text{phenyl}$ ,  $A = CH_2$ ,  $B = H$ ,  $R_3 = H$ ,  $R_4 = CH_3$  and  $R'_3 = (R_{15})_r$ -diazepinyl where  $R_{15} = H$ , the compound is classified in class 514, subclass 211.15;

For compound of formula (2):

When  $Y = \text{pyridyl}$ ,  $A = CH_2$ ,  $B = H$ , and  $R_4 = CH_3$ , the compound is classified in class 514, subclass 315;

When  $Y = \text{thienyl}$ ,  $A = CH_2$ ,  $B = H$ , and  $R_4 = CH_3$ , the compound is classified in class 514, subclass 438;

When  $Y = \text{furyl}$ ,  $A = CH_2$ ,  $B = H$ , and  $R_4 = CH_3$ , the compound is classified in class 514, subclass 461;

When  $Y = \text{pyridariny}$ ,  $A = CH_2$ ,  $B = H$ , and  $R_4 = CH_3$ , the compound is classified in class 514, subclass 252;

In addition, claims 1-30, and 32-40 are generic to a plurality of disclosed patentably distinct species comprising a disease or disorder which can be treated by stimulating, blocking, or inhibiting the activity of the FXR receptor.

For the diseases, which can be treated by stimulating, blocking, inhibiting the activity of FXR receptor, recited in the claim, encompassed a numerous disorders for example hypercholesterolemia, hypocholesterolemia, overproduction of bile acids, and underproduction of bile acids.

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Due to the structural diversity in active compounds herein and the different and unrelated natures of the disorders and causative factors therefor encompassed by the claims, the search for all species presents an undue burden on the office. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of a FXR ligand and a single disclosed species of the disease or disorder, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P. Sec. 812.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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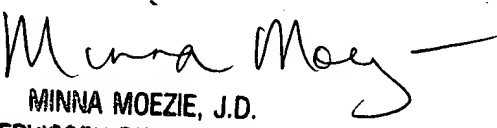
remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
June 20, 2001

  
MINNA MOEZIE, J.D.  
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